



The hidden values

transparency in decision-making processes dealing with hazardous activities

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PROJECT REPORT

THE HIDDEN VALUES

**Transparency in decision-making processes
dealing with hazardous activities**

Birgitte Rasmussen & Karsten Klint Jensen

DANISH CENTRE FOR BIOETHICS AND RISK ASSESSMENT

5

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FOREWORD

Transparency is a highly desirable feature of the recommendations and decisions made by public authorities on the use of chemicals, GMOs and other potentially hazardous products. Without it, the relevant political decisions may not be perceived as legitimate.

But it is no simple task to make the complicated technical basis of such decisions transparent to the rest of society. And when decisions involve political considerations it can be hard to clarify the criteria of political acceptability.

These difficulties notwithstanding, we believe that we have taken some important steps forward in the project “The Hidden Values - Transparency in Decision-Making Processes Dealing with Hazardous Activities”. The report seeks to shed light on what is needed to create a transparent framework for political and administrative decisions on the use of GMOs and chemical products.

It is our hope that the report’s recommendations will serve as a source of guidance to public authorities, politicians and others interested in increasing the transparency of decisions on GMOs, chemicals and other hazardous activities.

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CONTENT

Guidance and main results / 7
Background / 9
Transparency / 11
Overall value premises in risk decisions / 13
Complexity and uncertainty / 15
Risk assessment and risk management / 17
Mandate / 17
Hazard identification / 19
Hazard characterisation / 20
Exposure assessment / 21
Risk characterisation / 21
Risk decision / 24
Risk reduction and management / 26
Knowledge and communication in advisory processes / 29
Knowledge / 29
The science/policy decision-making process / 31
Scientific advisory structure / 32
Problem definition / 33
Scientific advice to policy-makers / 34
Hearings / 36
Draft positions to decision-makers / 37
Presentation and communication / 37
Closing remarks / 39
Acknowledgement / 40
References / 41
Appendix 1: Workshop and cases / 43
Workshop: 7 december 2004 / 43
Risk assessment of glyphosate resistant fodder beet / 43
Risk assessment of penta-bromo diphenyl ether / 44
Risk assessment of vanadium / 44
Appendix 2: Methodological basis and biographical notes / 47
Biographical notes / 47

GUIDANCE AND MAIN RESULTS

Lack of transparency in decision-making processes is often pointed to as an explanation of the evolution of controversies concerning risk. The aim of this report is to discuss the normative and factual premises in risk decisions with the purpose of working out recommendations on how to make these premises more transparent for third parties.

It is generally agreed that the risk analysis process contains three interacting elements: risk assessment, risk management and risk communication. Effective risk communication is a precondition of transparency, but from our point of view a prerequisite for transparency in risk communication is transparency in the two other elements of risk analysis, especially where the normative and factual premises are concerned. Therefore, we have chosen to address transparency in risk assessment and risk management. We shall put

less emphasis on transparency in risk communication.

This report contains theoretical parts concerning value premises, uncertainties and knowledge application in risk decisions which are supported by experiences from empirical studies and a workshop held on 7 December 2004. The theoretical parts are intended to explain the underlying rationale for our recommendations

The outcome of the project is a list of recommendations on how to improve transparency in risk assessment and risk management. It is our expectation that improved transparency in risk assessment and risk management will lead to improved transparency in risk decisions and risk communication.

Table 1 contains the key recommendations of the project.

Table 1. Summing up – key recommendations to improve transparency

The normative premises constituting the 'risk window' related to risk assessment, together with acceptance criteria, should be addressed through dialogue between policy-makers and risk assessors in order to achieve common understanding of **the mandate** for the risk assessment. We recommend the following points:

- which kind of decision is to be taken, and hence
- which form of conclusion is needed
- legal foundation
- concerns behind the question, e.g. suspected hazards etc.
- the criteria considered relevant
- levels for acceptable risk (if possible)
- expectations concerning the scope of the risk assessment
- explicit limitations
- attitudes concerning uncertainties

The **specific value premises** of an approval of a risky activity are presented by stating the identified hazards and their investigated adverse effects.

- risk characterisations for each adverse effect
- presentation of, and argumentation about, those hazards and adverse effects considered but ignored

An audit trail of the appraisal process should be made available to policy-makers, decision-makers, and ultimately stakeholders. The audit trail might cover the mandate; the generation of scientific questions; the scientific arguments; alternative scientific options and uncertainties; and the scientific appraisal of policy options.

Uncertainties are presented for each adverse effect to indicate alternative scenarios to the most likely risk characterisation together with an evaluation of the reliability of each of the alternative scenarios.

- the approval is supplemented by a statement explaining whether the precautionary principle has been applied in the light of identified uncertainties

Common understanding can be improved by face-to-face meeting between scientific advisers and policy-makers in all steps in the appraisal process, with special emphasis on the distinction between analysing scientific and normative premises; and the outcome of these meetings should be documented in an audit trail. Further, it is recommended that times and places for dialogue and participation (e.g. fairs, talk rooms, public meetings, conferences) be established.

Establishment of a **well-documented process** for identification and selection of scientific advisers, stakeholders (hearing partners) and expert committees.

It should be made clear both how the **hearing statements** will be used in the appraisal procedure and which topics will be commented on. Afterwards feedback indicating the impact of the hearing statements in the approval process should be returned to hearing partners.

Worries among stakeholders, including ethical worries, that are not addressed by the appraisal procedure should be pointed out, together with advice on where and how these worries can be discussed and treated.

Regular **exchange of experience between the jurisdictions** responsible for the regulation of risky activities can be constructive in order to help make the scientific advisory structure transparent.

BACKGROUND

Decision-making processes dealing with hazardous activities are a challenge to modern society. The risk debate has shown how a wide range of disparate issues, such as socio-economic impacts, ethical questions, utility value, and uncertainties, worries the public. Today the situation in Europe on risk issues can be characterised as government decisions on hazardous activities based on technocratic and scientific assessments often regarded as too narrow and not in compliance with the viewpoints of the public at large. Authorities and their scientific advisers are increasingly faced with the demand that approval decisions made on the basis of risk assessments should be more transparent. The main reason behind this demand is the apparently decreasing confidence among the general public – a decrease fuelled by controversial cases such as genetically modified crops and mad cow disease.

Loss of confidence is supposed to arise when science-based reassurances are proven wrong. It is reinforced when mistakes are not openly admitted or perhaps covered up. Another cause of loss of confidence is the experience among the general public that important worries are not being addressed, or that lay people are not being listened to, by the approval procedures.

Handling risks in a fashion that coheres with societal views and needs is one of the most challenging aspects of the risk management process. It involves considering not only the possible consequences of risk-taking and their likelihood, but also the respective merits and limits of the various options for risk reduction, how costs and benefits would be distributed among individuals, whether social values might be contradicted, and the state of knowledge and variety of standpoints regarding all these issues. This situation calls for discussions on how to perform decision-making in an open and transparent way that reflects social concerns, and it represents a challenge of great magnitude for modern society and democracy.

The demand for transparency is believed to be a first step on the way to regain confidence in the regulation of hazardous activities and the risk

assessments it is based upon. The aim is to increase knowledge of the decision procedures and their foundation. This increased knowledge is a precondition of sceptical members of the general public being able to exert influence on the political frame underlying decision procedures. Eventually, this might in the longer run then provide the basis for an informed and focused debate, and also ensure that decision procedures evolve so as to better meet the expectations of the general public. Raised transparency in the risk assessment process can also have the additional benefit of achieving more reliable final statements of risk, because transparency can help to ensure that relevant input is provided in the right steps of the assessment process.

A frequently mentioned implication of transparency is the functional separation between risk assessment and risk management, and more generally the demand for independent scientific advice. However, even though independence may reduce perceptions of vested interests in risk assessments, it cannot by itself renew confidence in the credibility of risk assessments.

First, since decisions are based on risk assessments, emphasising the independent scientific nature of risk assessments tends to signal, misleadingly, that decisions are made exclusively on scientific grounds. In fact, decisions are action-guiding, and as such they build on a normative foundation identifying adverse effects and the acceptable level of risk for the occurrence of these adverse effects. Indeed, since risk assessments are supposed to estimate the likely adverse effects of exposure to a given hazard, they presuppose this normative foundation in order to be meaningful.

Therefore, signalling that decisions are made exclusively on purely scientific grounds will obscure the normative foundation of the decision. Transparency must, on the contrary, allow the normative foundation of the decision – and consequently, the intimate interplay between facts and values in it – to be brought forward and presented clearly to the public.

Secondly, a large part of the loss of confidence in risk assessments arises from the fact that such

assessments seldom present their own limitations and uncertainties. Thus they give an appearance of being more comprehensive and certain than they actually are. The general public tends not to have full confidence in risk assessments because they see that, over recent years, a number of unconditional reassurances about complete safety have later been proven wrong by the facts. Hence, it will in general not be perceived as credible if a risk assessment pretends to guarantee absolute safety or absolute certainty about its conclusions – regardless of the evidence these conclusions are based upon.

The demand for transparency thus makes it necessary that the normative and factual premises of a decision are presented in a clear way. Particular focus should be on the normative foundation of the decision and how it interacts with the risk assessment. A special challenge is to present the uncertainty inherent in the decision and the attitude to this uncertainty taken in the decision – e.g. whether or not the Precautionary Principle has been invoked.

Transparency in this sense demands new efforts from the policy-makers and the scientific experts who establish the input of a decision. The aim of this report is to make suggestions as to how increased transparency can be obtained at all stages of a generic decision on a hazardous activity, product or process.

We should like to point out that, although transparency has become almost a buzz word, it might in practice be met with resistance. Transparency makes policy-makers and scientific advisers open to public scrutiny and thus vulnerable to criticism, and they might want to avoid this. Also, transparency is likely to make it clear for the public that decisions are based on a more limited and uncertain foundation than the present appearance indicates. Policy-makers might fear that, rather than increasing trustworthiness, this might actually create more concern among the public.

In addition, transparency makes the authorities' and experts' responsibility as decision-makers much more visible. Once again, this makes policy-makers and their scientific advisers open to criticism, and they might want to avoid this. Finally, transparency is likely to leave less room for political discretion, and politicians might not want that. We shall try to keep these opposing interests to transparency in mind in the following.

Our paradigmatic case is decisions about genetically modified organisms (GMOs). However, we

shall consider other cases as well, even though they might involve other kinds of decision. The report refers to a European context and it uses examples from this context. However, we hope the discussion is sufficiently general to be of interest for other contexts as well.

TRANSPARENCY

We define transparent decision-making as decision-making in which the decision-maker clearly presents to others the normative and factual premises behind his conclusions and explains the reasoning leading him from these premises to the conclusion. Transparency thus involves uncovering, describing, documenting and communicating all the argumentative steps in the line of reasoning and the weighting of evidence leading to and justifying the final decision. Doing this properly also means taking into account limitations, weaknesses and uncertainties, as well as pointing at issues which – even though they might be considered relevant from the perspective of some stakeholders – are not addressed by the decision process.

Our main suggestion is that each decision should be accompanied by a paper (audit trail) describing the premises justifying it. Transparency in this sense demands new efforts from the authorities and the scientific advisers who establish the input of a decision. Consequently, it will be necessary to investigate the stages of the generic decision procedure in order to clarify how the different actors at each stage can contribute to better transparency during the procedure leading up to the final decision.

Transparency is often identified with openness in the sense that meetings are public and all relevant documents are accessible to the general public. However, even though openness is important – it must indeed be considered a precondition for transparency – it is not by itself sufficient. Transparency also requires the basis of the decision to be made explicable and understandable for third parties. In our view, this is achieved by presenting the normative and factual premises behind the decision and by explaining how the decision follows as a practical conclusion from these premises. Hence, we shall concentrate, in our discussion of transparency, on the content of decisions and its context, rather than on openness and other circumstances surrounding the decision-making process.

Transparency is also often defined as a partici-

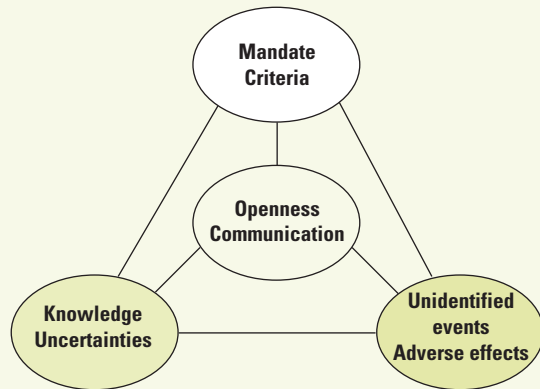
patory process involving the public or stakeholders. However, we see no necessary logical connection between the concept of transparency as defined above and participation. A transparent decision may or may not involve participation of the general public or stakeholders. Therefore, we prefer to keep the issue of participation distinct from the discussion of transparency as such. But of course we shall consider the role of participation in generic decisions about hazardous activities, products or processes.

Further, variations in risk terminology have been identified as a barrier for transparency. From our point of view, variations in risk terminology are important for the understanding and management of risk issues, as they can be a source of confusion. Thus, we strongly support the ongoing attempts to harmonise terminology (European Commission, 2000) and we shall ourselves use this terminology.

Thus, achieving and improving transparency must involve:

- Normative premises addressed by the approval procedure and the argumentation behind them.
- *Mandate and criteria* for the risk assessment, i.e. a specification of *unintended events and adverse effects* displaying the risks addressed by experts in a specific risk assessment.
- Factual premises and argumentation comprising *knowledge* with related *uncertainties* generated for the preparation of the risk assessment.
- *Openness and communication* with third parties requiring channels and forums for spreading and discussion of the material.
- These four interacting dimensions in transparency concerning risk decisions are illustrated in Figure 1.

Figure 1. Dimensions in transparency and risk decisions



OVERALL VALUE PREMISES IN RISK DECISIONS

In this report, a generic decision on a hazardous activity, product or process, is concerned with whether or not the activity, product or process in question should be allowed or disallowed; and in the former case, whether or not risk reducing measures should be imposed.

A generic decision has its warrant in the legislation. Usually it is made by an EU authority; however, national authorities or governments may be involved in the decision process. The decision will be based on a risk assessment. Hence, it can be viewed as a form of risk management decision.

If we look at the kinds of decision that are the main subject of this investigation, we observe that they are decisions made by the authorities about approval (sometimes conditional) or disapproval of hazardous activities, processes or products. Thus, the conclusion of the practical argument we are about to reconstruct is either the statement that the activity, process or product in question should be approved of, possibly on condition of certain risk management requirements, or the statement that the activity, process or product should be disallowed.

Basically, it takes two premises to justify a conclusion like this. One is a normative premise to the effect that activities, processes or products involving a risk to human health or the environment above an acceptable level only should be allowed if suitable risk management interventions can be imposed to reduce the risk to an acceptable level; otherwise they should not be allowed. The other premise is a factual premise stating whether or not the risk to human health or the environment of the activity, process or product in question is above or below the acceptable level.

A decision on a normative premise of the first kind is a political decision. The second, factual premise stems from the conclusion of a risk assessment performed by independent scientists. Finally the competent authorities draw the conclusion that follows from these premises.

Thus, the simple logic of a decision of approval looks like this:

- *Value premise:* Activities, processes or products

should be allowed only if they involve a risk for human health or the environment lower than the acceptable level; they should be disallowed if they involve a risk for human health or the environment higher than the acceptable level.

- *Factual premise:* This activity, process or product involves a risk for human health or the environment that is lower than the acceptable level (higher than the acceptable level).
- *Approval decision:* This activity, process or product should be allowed (should either be banned or be allowed on condition of risk management interventions that reduces the risk to an acceptable level).

The division of labour suggested by the argument is important from the point of view of democratic legitimacy. Political decisions should be open to democratic control. Hence, they should only be made by people appointed to a political responsibility. In principle, scientific advisers should provide exclusively factual input to the decision, but in practice they interpret and apply the value premises during the preparation of scientific advice. The scientific advisers as well as the policy-makers should be aware of this two-sided input from scientific advisers. Presenting the premises of a decision in a transparent manner is a way of making it open to public scrutiny.

COMPLEXITY AND UNCERTAINTY

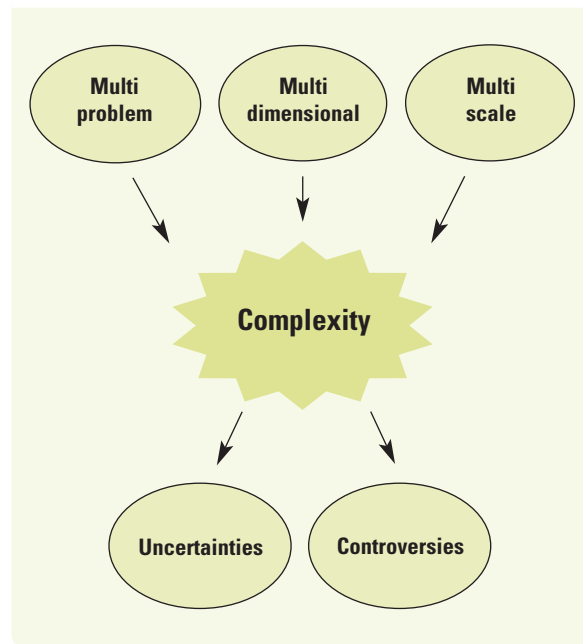
Complexity and transparency in regulatory appraisal may be regarded as being in tension. It can be a big challenge for a policy-maker to present, to third parties, a complex problem and decision situation in an easy and understandable way. Policy-makers and decision-makers have to face and be aware of the fact that the complex character of risk issues is an underlying, key reason why risk decisions are hard to present and understand and consequently are often criticised for lack of transparency.

There are many senses of complexity which have to be sorted out in order to make the risk assessment more transparent. Focusing on transparency in the approval decision, we choose the line of attack proposed by van Asselt (2000). This says that complex decision-making is characterised by:

- multi-problem: there is not one problem, but a tangled web of related problems
- multi-disciplinary/multi-sectoral: the issue lies across or at the intersection of many disciplines and sectors
- multi-scale: the underlying processes interacting on various scale levels (local, regional, national, continental and global) and on different temporal scales

Due to the multidimensional character of complex decisions, transparency is complicated for two major reasons. First, decision-making on complex issues implies consideration of an increasing variety of often conflicting and contradictory perspectives, interests and needs. Second, complexity goes hand in glove with fundamental uncertainty. The complexity of the decision situation is illustrated in Figure 2.

Figure 2. Complex decision problem



Uncertainty in science and decisions has led to much confusion among the public. A better understanding and description of uncertainty and how it is dealt with in approval decisions is a prerequisite for transparent decision processes. Van Asselt (2000) proposes a taxonomy of uncertainty that distinguishes between source and type of uncertainty.

Source refers to the origin of uncertainty, which implies that such a classification is preferably universally valid. On the highest level of aggregation sources of uncertainty have both an ontological (variability) and an epistemological (lack of knowledge) dimension.

Type refers to the way in which uncertainty manifests itself in a particular context. The consequence is that any typology of types of uncertainty is by definition context-dependent or method-dependent. Uncertainty enters various steps of the modelling process. This can be described by the following classification:

- *Technical uncertainties* arising from the quality or appropriateness of the data used to describe the system.
- *Methodological uncertainties* arising due to lack of knowledge.
- *Epistemological uncertainties* concern the concept of the phenomenon. This type of uncertainty arises from structural uncertainty and variability.

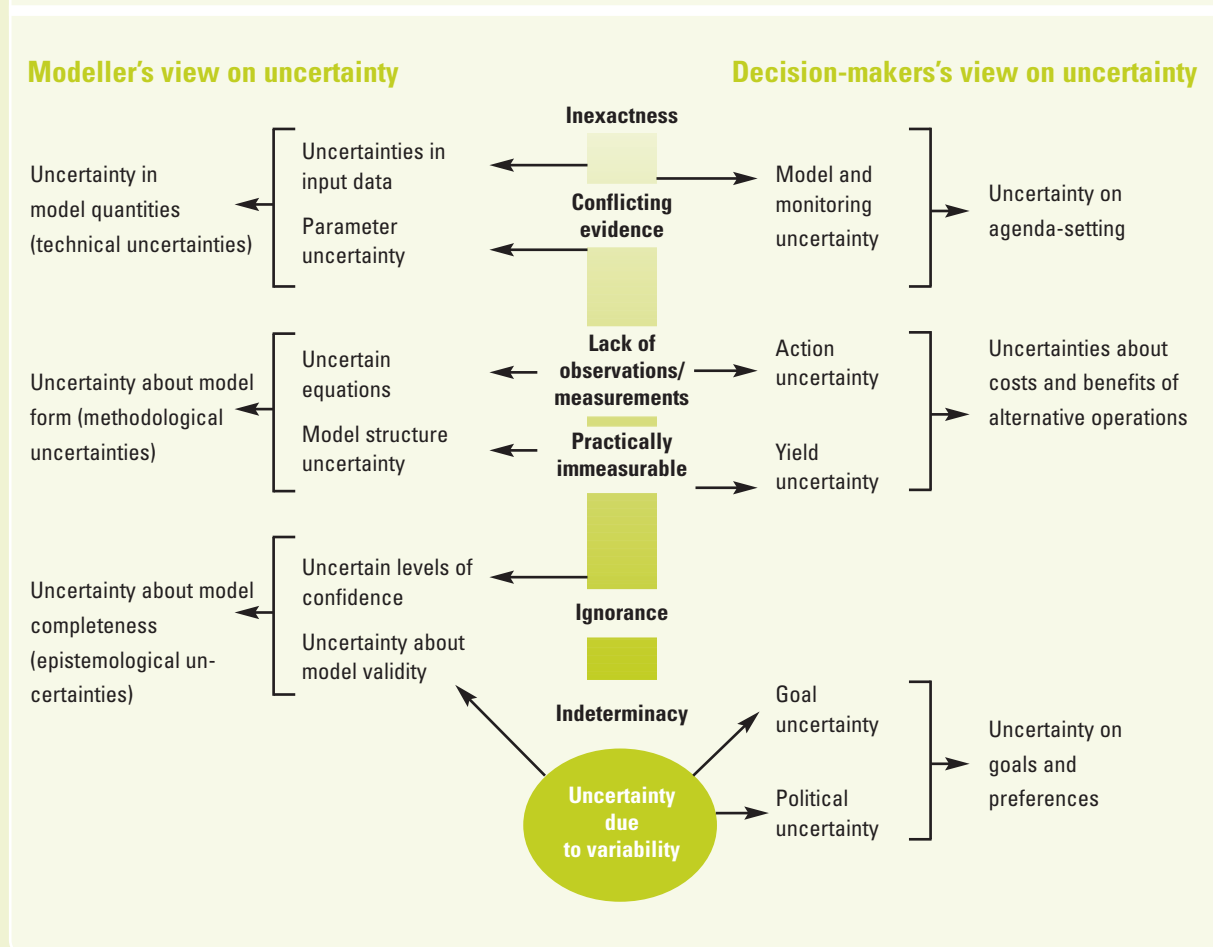
Another typology of uncertainty relevant in the context of science for decision-support is a classification of uncertainty by its focus in the decision-making process:

- *Action uncertainty*, a decision-maker may be uncertain with respect to the composition of the set of alternative options.

- *Yield uncertainty* due to uncertainty with respect the costs and benefits of the alternative options.
- *Goal uncertainty*, i.e. uncertainty or ambiguity about the preferences or goals the decision-maker aims to satisfy.
- *Political uncertainty* due to many conflicting objectives, priorities and interests.

Uncertainties in the modeller's and decision-makers view are illustrated in Figure 3. Model and monitoring uncertainties are usually dominant in the ignition and agenda-setting phase. Action and yield uncertainties may play a vital role in the assessment phase, while political uncertainties dominate the actual decision-making process.

Figure 3. Uncertainty in the modeller's and decision-makers view (van Asselt, 2000)



RISK ASSESSMENT AND RISK MANAGEMENT

The process of risk assessment and risk management is normally triggered through the formulation of a problem for which a decision is needed. Prior to the risk assessment a problem-framing process takes place. This is not solely a scientific process; it is also a policy process identifying the issues to be addressed in the risk assessment. Following the risk assessment, risk decision and risk management take place. The entire process is shown in Figure 4.

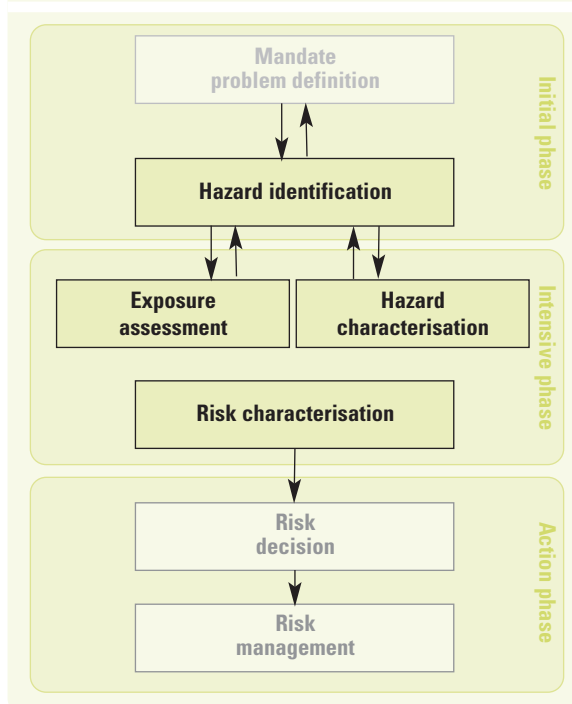
Risk assessments are conducted to estimate the consequences, in terms of adverse effects to human health or the environment, that can be expected from exposure to given risk agents, and to assist in judging whether these consequences are significant enough to require increased management or regulation.

Risk assessments vary widely in scope and complexity, depending on the application. They range from simple screening analysis to major analytical efforts that require years of work and substantial budgets. Despite these variations and differences, some main, generic task and elements are common to the majority of risk assessment procedures. These influence the transparency of scientific as well as normative and policy issues. Risk assessment is generally described as consisting of four main steps (European Commission, 2000):

- **Hazard identification:** The identification of a risk source(s) capable of causing adverse effect(s)/event(s) to humans or the environment species, together with a qualitative description of the nature of these effect(s)/event(s)
- **Hazard characterisation:** The quantitative or semi-quantitative evaluation of the nature of the adverse health effects to humans and/or the environment following exposure to a risk source(s). This must, where possible, include a dose response assessment.
- **Exposure assessment:** The quantitative or semi-quantitative evaluation of the likely exposure of man and/or the environment to risk sources from one or more media.
- **Risk characterisation:** The quantitative or semi-

quantitative estimate, including attendant uncertainties, of the probability of occurrence and severity of adverse effect(s)/event(s) in a given population under defined exposure conditions based on hazard identification, hazard characterisation and exposure assessment.

Figure 4. The entire process of risk assessment and risk management



Mandate

Scope and problem definition

Typically, an EU directive or national law will prescribe an approval procedure and the conditions for approval in general terms. Thus, legislation will prescribe that the decision should be based on a scientific assessment of the risk of adverse effects on human health or the environment. It is of course implied that approval is conditional on the risk of such adverse effects being sufficiently low. Even though the general expression 'adverse effects on human health or the environment' leaves a lot of

room for interpretation about which precise type of adverse effect should be considered, it does, nevertheless, roughly demarcate the kinds of consideration that can enter into the decision.

Recommendations to improve transparency

The point of the mandate is that the decision context into which the risk assessment enters should be illuminated as far as possible in advance. We recommend that the following points be addressed:

- which kind of decision is to be taken, and hence
- which form of conclusion is needed
- legal foundation
- concerns behind the question, e.g. suspected hazards etc.
- the criteria considered relevant
- levels of acceptable risk (if possible)
- expectations concerning the scope of the risk assessment
- explicit limitations
- attitudes concerning uncertainties

Decisions about what are to count as adverse effects on human health or the environment, and what level of risk of the occurrence of these effects is unacceptable, are delegated to the discretion of the competent authorities. These decisions make up the value premise of an actual decision. Thus, an actual decision is based on a risk assessment of a number of potential hazards. The risk assessment concludes in a characterisation of the risk for the specific adverse effects each of these hazards is assumed to have a potential for. The decision then states whether or not this overall level of risk is acceptable.

How can this value premise be presented in a clear way?

Our recommendation is that it should be reported, in a systematic way, which hazards have been examined, and which risk characteristics concerning specific adverse effects each of them gives rise to. This should be done for each of the alterna-

tive acts (typically a ban or an approval on certain conditions) that are under consideration.

In other words, the proposal is that a decision matrix should be set up in which the expected consequences of each of the acts under consideration is described in terms of the criteria that enter into the decision (see Table 2). The criteria for the decision are precisely the adverse effects actually taken into consideration. The expected consequences in each case are given by the conclusion of the risk assessment, i.e. the risk characterisation. An example of what this matrix looks like is given in Table 3. The example is based on the case of GM fodder beet as described in Appendix 1. Note that the risk assessment in this case explicitly considers the risks of using GM fodder beet instead of non-modified beet (the difference between approval and ban, so to speak).

The point of the proposal is that all the elements that actually enter into the decision are presented systematically and clearly. Hence, it is implied that effects that are not in the list have not been taken into consideration. This makes it possible for outsiders to know whether or not some consideration or other has been dealt with.

A decision matrix like this should be supplemented with two things. First, it should be stated separately whether certain potential hazards or certain possible adverse effects have deliberately been excluded, e.g. because they are considered to be completely unlikely. Thereby it is signalled that the worry in question has been considered but eventually not taken into serious consideration. This makes it possible for an outsider to infer that possible effects that are not mentioned at all have not been considered.

Second, the reasons underlying the final choice of act should be described. In so far as quantitative criteria of acceptance have been used, they should of course be reported. Otherwise, it should as far as possible be made clear which considerations the decision put weight on in the judgement of whether or not to find approval acceptable.

Table 2. Decision matrix

Criteria	Adverse effect 1	Adverse effect 2	Adverse effect 3	...
Acts				
Approval	Risk characterisation 1	Risk characterisation 2	Risk characterisation 3	
Ban	Status quo	Status quo	Status quo	

Table 3. Decision matrix - an example using the GM fodder beet case

Criteria	Toxic effects of the produced enzyme	Allergenic effects	Health risks from using the beet to food production	Invasion of the modified fodder beet outside cultivated areas	Hybridisation with the wild relative Beta maritima	Spread of the resistance gene to weed beet
Difference to use of non-modified fodder beet	No documented effects	No documented effects	No documented effects	No reason to expect ecological consequences	No reason to expect ecological consequences	Good practice recommended

Hazard identification

Aim and characteristics

The objective of hazard identification is to establish a causal link between a risk source and an adverse effect. The identified hazards thus make up the fundamental demarcation of a risk assessment problem, and the risk assessment will – on the basis of further premises involving hazard characterisation and exposure assessment – lead to a conclusion about the hazard in question in the form of a risk characterisation.

Hazard identification is merely a qualitative exercise. The quantitative assessment is the subject of exposure assessment and hazard characterisation.

In practice the hazard identification phase is seldom a distinctive part of the risk assessment. It can be viewed as a further scope-defining part of the objectives of the risk assessment. It is significant to establish a close correspondence between the hazard identification and the previous and the subsequent steps of the risk assessment process.

Problem-framing and hypotheses

The word ‘hazard’ is central and often a subject of disagreement. Hazards can be viewed as acts and phenomena that have the potential to produce harm or undesirable consequences to humans and what they value. Hazards may come from physical phenomena (such as radioactivity, sound waves, magnetic fields, fire, floods, explosions), chemicals (ozone, mercury, dioxins, carbon dioxide, drugs, food additives), organisms (viruses, bacteria), commercial products (toys, tools, automobiles), or human behaviour (drinking, driving, firing guns). Hazards can also come from information (e.g. information that a person carries a gene that increases his or her susceptibility to cancer may

expose the person to job discrimination or increased insurance costs) (Stern & Fineberg, 1996).

Identification implies an exploration of acts and phenomena, a choice of those considered capable of causing adverse effect(s)/event(s), i.e. hazards, and the putting to one side of those not considered capable of causing adverse effect(s)/event(s).

‘Risk window’ – systems thinking

Hazard identification is closely connected with the delimitation of the system. A risk assessment views the world through a ‘risk window’ that only makes visible that which has been predefined as a relevant risk, i.e. the demarcation in space and time of the possible adverse effects to be assessed and the choice of hazards to be assessed for possible adverse effects (Jensen et al., 2003). It should be stressed that the process of defining a ‘risk window’ consists of a number of choices, so transparency pertaining to the defining process and its basic assumptions is crucial.

Defining a ‘risk window’ is in systems-thinking terms equal to defining system boundaries, e.g. temporal boundaries, geographical boundaries, impact assessment boundaries. Impact assessment boundaries are essential as this type of boundary defines the types of concern that are addressed (or not addressed) in the risk assessment. It is important to briefly say why issues are left out. E.g. organic farmers have argued that a legitimate concern is the impact on their production of genes spread from modified crops to organic crops; this type of impact is normally not considered in risk assessments of genetically modified crops.

In relation to risks, the notion of systems also emphasises the transmission mechanism through

which an initial disturbance amplifies, spreads inside or even beyond given boundaries, interacts with other disturbances and ultimately alters the functioning of a process. The system in question thus involves the various components of an unexpected event: the causative event, repercussions and final consequences. Hence, system demarcation is of importance not only for the system boundaries but also for the understanding of the system's dynamics and thus for the assessment of consequences and probabilities.

Setting up reliable hypotheses

Hazard identification depends on setting up reasonable hypotheses; and as is well known from the philosophy of science, there is no systematic way of generating true hypotheses. Hazard identification can be based on guidelines, checklists, experience from previous risk assessments, reports on undesired events, group sessions etc. In some cases, it is possible to work one's way backwards from a well-defined type of adverse effect, through a number of consecutive steps of necessary conditions for this effect to occur, to the identification of a hazard. In other cases, a hazard under suspicion can be tested for the effects it leads to. But these methods depend to some extent on the researcher already knowing what he should look for. Hazard identification therefore depends a lot on the competence, imagination and creativity of the risk assessors.

The crucial element of hazard identification is the choice of what should be considered adverse effect(s)/event(s). The uncertainty this involves will be greatest in the case of new activities, processes or products with which there is little or no experience. It will be less pronounced in the case of items with which there is more experience. In terms of transparency, it will be impossible to list hazards not yet identified.

The upshot is, however, that there is no way to ensure the completeness of a specific hazard identification.

Recommendations and perspectives

The main problem related to transparency is not the normative character of hazard identification, but to explain how hazards have been explored, evaluated and finally selected/ignored. The only possibility is to report the attempts that have been made to identify relevant hazards, and the consideration involved in ensuring the highest possible level of completeness.

The presentation of the outcome of a hazard identification contains three main elements: a) the reason why certain acts and phenomena have been identified and viewed as hazards, i.e. being capable of causing adverse effect(s)/event(s); b) the reason why certain other acts and phenomena have been considered but viewed as being harmless; and c) discussion of (technical, methodological and epistemological) uncertainties related to hazard identification and how these have been taken into account during the hazard identification process. This can be expressed in tabular form:

Acts and phenomena	Adverse effects considered	Adverse effects ignored	Uncertainty

Hazard characterisation

Aim and characteristics

The hazard characterisation seeks to identify the quantitative relationship between exposure to the risk source and the nature and extent of the adverse effect (on human health or the environment), possibly in the form of a dose response curve.

Hazard characterisation is sometimes referred to as "effects assessment" or "dose-response assessment".

Uncertainties and dilemmas

Data – quality, availability, applicability

Hazard characterisation is typically based on testing of some form or other. Often, however, there are severe practical, economic or moral limits to the kind of testing that can be done. For instance, it is in general not possible to conduct toxicological testing on humans. Instead, animals are used.

The hazard characterisations based on data obtained from test systems, or from field and epidemiological studies on humans or ecosystems, may be supported by estimates derived from computational methods. On top of this, there is the problem of transferring the results obtained in limited experimental settings to the relevant context, e.g. transferring animal test results to human conditions. This transfer will often be surrounded by great uncertainty and be a source of conflict

and controversy. Therefore, the hazard characterisation is strongly affected by the quality and availability of data, and by the coverage, completeness and uncertainty of methods and models.

Thresholds

In the hazard identification phase, various thresholds or trade-off levels concerning adverse effects have to be established. Scientific evidence can underlie these thresholds, but often lack of knowledge means that the thresholds are determined in other, less transparent ways, e.g. by the introduction of safety factors, or by comparison with similar compounds or situations.

Recommendations and perspectives

Transparency related to hazard characterisation must address argumentation connected with, and documentation of, the established thresholds. The argumentative part will contain a presentation of reasons for the thresholds concerning adverse effects together with a presentation of conflicting viewpoints. The documentation will present the data used and the methods and models, together with a thorough discussion of the related (technical, methodological and epistemological) uncertainties, and how these may affect the trade-off levels and consequently also the final decision.

Exposure assessment

Aim and characteristics

The steps involved in exposure assessment vary widely, because circumstances differ with respect to how much is known about existing exposures and what data and information are available. A commonly used approach in exposure assessment uses evaluative or interpretative scenarios.

Uncertainties and dilemmas

Exposure assessment depends heavily on the availability of relevant measurement data or estimated modelling data. Measurement data can often be rather expensive to generate, whereas modelling data often are relatively cheap to obtain. In most cases, therefore, exposure assessments will have to be based on some form of modelling, based on a number of assumptions. As a consequence, a good deal of what is done is derived from models and from generalised assumptions about relevant physical parameters and human behaviour. This is of course also surrounded by some uncertainty. The main question with measurement data is whether

they are representative for the exposure scenario in question. Modelling data may sometimes be rather uncertain, depending on model assumptions, model complexity, data quality etc.

Lack of knowledge about actual exposure is one of the weaker links in the knowledge chain supporting risk assessments. Lack of knowledge comprises, beyond data quality, also understanding of the dynamics within the system and consequently also the scenarios in question. What concerns transparency in the exposure assessment phase key challenges are: 1) explanation and presentation of scenarios describing exposure pathways, doses, vulnerable objects, causal relations, likelihood etc., and 2) presentation of the impact of assumptions and uncertainties in the scenario development.

Recommendations and perspectives

Scenarios can be a useful and transparent way to present the outcome of an exposure assessment, because it is possible in scenarios to show pathways, causal relations, vulnerable objects etc. A weak point here, however, is the discussion and presentation of pathways, causal relations etc. that are not included in the scenarios but were considered during the exposure assessment. In a comprehensive documentation for the exposure assessment these considerations will appear as a supplementary part of the argumentation for the selected scenarios.

Risk characterisation

Aim and characteristics

The risk characterisation is the concluding task. It combines the principal findings of the hazard identification, hazard characterisation and exposure assessment in an integrated picture of the nature and expected frequency and severity of adverse effects in exposed populations and ecosystems.

The 'bottom line' forthcoming from the risk characterisation is a primary determinant of the risk decision and management phase following the risk assessment.

Uncertainties and dilemmas

The risk characterisation builds on the previous phases, and the uncertainties are therefore carried over into, and aggregated in, the risk characterisation. The level of uncertainty in risk assessments is in many cases much higher than that accepted in

pure science. Whereas pure science is a more or less unending search for truth, the objective of risk assessment is to provide the foundation for a practical decision about approval or disapproval of some activity, process or product. As such, risk assessment is constrained by a range of limitations stemming from the decision context: e.g. the conclusion has to be delivered within a limited time frame and the assessment has to be conducted on a limited budget; furthermore, practical obstacles and moral constraints seriously limit what kind of experiments can be performed.

In pure science, there is time to wait for uncertainties to be resolved. The authorities who require, and will depend on, a risk assessment, on the other hand, do not have this length of time to wait. They will have to act on the information that is available within reasonable time and budget constraints, however limited. Since the objective of the risk assessment is to provide information for a practical decision, the assessment has to be guided by values that are instrumental for this decision. The question is not so much 'When is a hypothesis sufficiently justified for it to be accepted as very likely to be true?', but rather 'When is a risk sufficiently characterised for the choice of action?'

It is very important for the policy-maker to know about uncertainty (including the different types of uncertainty and their sources (see Figure 3)). Suppose, for a moment, that risk assessments only reported the most likely hypothesis. The decision rule known as 'maximising expected utility' is normally characterised as being risk neutral – that is, it recommends indifference between getting some value for certain or choosing a lottery with a possible better and a possible worse result, but with the same expected (i.e. probability weighted) value. The idea of 'maximising expected utility' is to give some weight to unlikely outcomes by weighing them with their probability. However, a procedure based on only the most likely outcomes will ignore unlikely outcomes. Hence, it will necessarily take a risk seeking attitude; that is, it will run even greater risks than a risk neutral attitude maximizing expected utility would. But the authorities are expected to take a precautionary attitude to risks, i.e. a more risk averse attitude than just maximising expected utility. Clearly, they cannot simply ignore unlikely outcomes.

The decision that the evidence is sufficiently strong to warrant the scope and purpose of the risk assessment is always a matter of judgement. In

most cases, risk assessors have to conclude on the basis of already collected data and cannot wait for more evidence. They are obliged to accept a trade-off between reducing the risk of false positives, i.e. the risk of accepting a false hypothesis, or reducing the risk of false negatives, i.e. the risk of rejecting a true hypothesis – for it is not possible to reduce both. Policy-makers, therefore, need to consider whether or not to act on uncertain possibilities. The uncertainty of the choice situation makes it necessary for risk assessors to characterise the evidence for each possible hypothesis and the likelihood of its being true. This might run up against one of the virtues often associated with pure science: the conservative burden of proof. In pure science, the risk of false positives is often considered more important than the risk of false negatives. However, the authorities have to show precaution. Consequently, they have to take seriously the possibility of an unlikely hypothesis being true. Therefore, in order to serve the decision-makers, risk assessors should put more weight on the risk of false negatives than they would do if they were engaged in a scientific investigation with pure science as its objective.

Recommendations and perspectives

The main problem in this phase seems to be how to handle, evaluate and present the uncertainties. In practice some of these uncertainties are ignored in order to reach a conclusion. Therefore, it is important, in the presentation of the conclusion, to state clearly which uncertainties have been considered significant and which have been ignored.

In our view, one way to present the uncertainties is to describe in an exhaustive way relevant, mutually exclusive alternative hypotheses affecting the final choice. This suggestion is based on decision theory, and the notion of uncertainty involved corresponds roughly to "uncertainties about costs and benefits of alternative operations" in Figure 3. By hypotheses affecting the final choice, we mean combinations of exposure scenarios and dose response hypotheses, each leading to a conclusion about the frequency and severity of adverse effects for the choice of a given action. There are three reasons for taking this view. First, it is the aggregated uncertainty in the final choice that is relevant for the decision-maker. Secondly, listing the alternative hypotheses forces both risk assessors and policy-makers to consider also unlikely possibilities. Thirdly, an exhaustive list makes it easier to ensure that the ascription of probabili-

Table 4. Example of a choice situation based on a risk assessment presenting alternative hypotheses

Acts \ States of the world	The activity, process or product is causally related to adverse effects			The activity, process or product is <i>not</i> causally related to adverse effects
	Scenario 1	...	Scenario <i>n</i> -1	Scenario <i>n</i>
Allow the activity, process or product	Serious consequences for human health and/or the environment	...	Fewer implications for human health and/or the environment	No implications for human health and/or the environment
Do not allow the activity, process or product	Quite a few implications for human health and/or the environment Costs of preventive and remedial measures	...	Very few implications for human health and/or the environment Costs of preventive and remedial measures	No implications for human health and/or the environment Costs of preventive and remedial measures

ties to the different hypotheses is consistent, i.e. that the probabilities add up to a total of 1.

Table 4 contains an example of a choice situation based on a risk assessment presenting alternative hypotheses. The table illustrates a simplified choice situation with uncertainty about the causal relations between a certain activity, process or product and a certain set of adverse effects. Each of the scenarios represents different combinations of exposure and dose response relationship. Depending on the actual state of the world, i.e. the true scenario, the choices of allowing or banning the activity, process or product in question will have the consequences outlined. The consequences are described by the risk characterisation, given that a specific scenario hypothesis is true, plus the estimated costs of choosing the precautionary action.

The uncertainty is that the actual state of the world (i.e. the true scenario) is not known at the time when the choice has to be made. Perhaps probabilities can be assigned to each of the scenarios, indicating how likely they are to be true. If there is only a little uncertainty, one of the scenarios is very likely to be true. But even so, it might be helpful to consider certain rather unlikely scenarios.

By way of example, consider the matrix that can be uncovered from the Southwood Working Party's risk assessment concerning BSE in 1988 (Jensen,

forthcoming): see Table 5. The uncertainty in this case concerns hazard identification, i.e. whether or not a causal connection exists between the BSE agent and a Creutzfeld-Jacob-like disease in humans. However, even though the uncertainty in this case is great, it is possible to consider certain scenarios in which BSE can be transmitted to humans. We can imagine high or low exposure, and we can imagine that a low or a high dose of infected material is infectious. This gives us the following table (in which the risk characterisations are mere stipulations by us), where uncertainty about exposure and dose-response are added to the picture and finally "added up" (see Table 6). One point about systematic consideration of uncertainty is that, when one does this, certain critical questions may become apparent. Thus, in this case, it seems clear that the size of the infectious dose might be rather important. Perhaps this insight might have triggered animal experiments on this matter at an earlier stage. Such experiments were in fact conducted at a rather late stage.

Table 5. Risk assessment of BSE

Acts	Hazard	BSE can be transmitted to humans	BSE <i>cannot</i> be transmitted to humans
Do nothing		Extremely serious consequences for human health	No consequences for human health
Precautionary measures		Limited consequences for human health Costs of preventive and remedial measures	No consequences for human health Costs of precautionary and remedial measures

Table 6. Scenarios in the event that BSE can be transmitted to humans

Acts	Scenarios	High exposure Low infectious dose	High exposure High infectious dose	Low exposure Low infectious dose	Low exposure High infectious dose	BSE <i>cannot</i> be transmitted to humans
Do nothing		Extremely serious consequences for human health	Limited consequences for human health	Serious consequences for human health	Limited consequences for human health	No consequences for human health
Precautionary measures		Limited consequences for human health Costs of precautionary measures	Almost no consequences for human health Costs of precautionary measures	Few consequences for human health Costs of precautionary measures	Almost no consequences for human health Costs of precautionary measures	No consequences for human health Costs of precautionary measures

Risk decision

Approval

The purpose is to give authorisation to (or withhold it from) the hazardous activity, and to declare the conditions and restrictions under which the hazardous activity must be operated.

Dilemmas and concerns

How can the choice of an acceptable level of risk be justified? The choice involves controversial issues, and this is exactly the reason why it is important for policy-makers to be able to justify the final choice.

The choice is a choice between alternative acts,

including different risk management strategies. Hence, the considerations involve a comparison of the possible consequences and their likelihood for each possible act. The act to choose is the act which – with sufficient certainty – ensures an acceptable level of occurrence of adverse effects. But how is this level to be determined?

Uncertainties are also related to the decision situation (see Figure 3). There might be uncertainties related to agenda-setting, risk acceptance criteria, conflicting objectives, priorities and interests. We have no clear recommendations that concern these types of uncertainty. We can only stress that an approval/disapproval is taken on a specific understanding of the decision situation, and that

this understanding should be presented as transparently as possible.

In the absence of other considerations, there is a natural tendency to require the lowest possible risk level. If a lower level could be achieved, how can a higher level be justified? In order to block this logic, the first report on the harmonisation of risk assessment procedures (European Commission, 2000) suggested that assessments of benefits be incorporated into risk assessments. The idea is that for an activity, process or product involving great benefits, it might be reasonable to run a greater risk than it would be for an activity, process or product involving only slight benefits. Indeed, ordinary theories of decision-making under risk or uncertainty would deem it irrational not to consider the likely benefits of the envisaged activity, process or product when determining the acceptable level of risk.

However, for legal reasons it is not clear to what extent this can be done. Thus, the present approval procedure for GMOs, as prescribed by the Directive, is exclusively concerned with the assessment of risk of adverse effects. It does not mention the assessment of possible benefits. This reflects the liberal foundation of GM regulation (Jensen, 2002). The job of the state is only to protect its citizens against harms and to reduce the risk of such harms. Beyond this, people and companies have a right to choose for themselves. Authorities which, on the basis of an assessment of expected benefits and their comparison with risks, make choices on the citizen's behalf would be acting paternalistically; and there might be legal limit on how far this is possible.

An important consideration is comparison with the level of acceptable risk in other areas. If the constraints in one area are either much more or much less strict than in other comparable areas, this is likely to be experienced as unjust differential treatment. On the other hand, the choice of areas in which approval based on risk assessment is required is to a large extent the outcome of political processes. In these processes, new, unknown and controversial technologies tend to be prominent. Equality before the law might then conflict with the democratic duty to make decisions in accordance with the public's wishes.

Risk assessments of emerging technologies are often characterised by lack of norms and standards. Consider the deliberate release into the environment of GMOs. Here, indirect effects, delayed effects and cumulative long-term effects are

situated in a grey area in which lack of knowledge and experience makes them difficult to identify and consequently also to assess and operate. For these types of technology it may be pointless, and perhaps impossible, to define clear limits for unintended and adverse effects (Kjær, 2004). Here it is important for experience to be collected and evaluated case by case in order to improve the criteria set for future risk assessments. But here it is also important to be aware of that setting criteria case by case can lead to differences from case to case, and consequently from one application to the other, concerning the normative premises for the approval decisions.

Certain kinds of consequence, such as death or irreversible harm to the environment, raise serious problems in determining a level of acceptable risk. If the risk cannot be reduced to zero, which is almost always the case, some level of risk of death, e.g., will have to be accepted; but what level? In some areas, there are quantitative levels of acceptable fatality. However, there is no clear consensus about how this level should be determined; and in many areas the thought of accepting that some number of people will die is very controversial.

The 'Precautionary Principle'

Uncertainty about the consequences of the decision raises further ethical and political questions for the authorities. Preventive or remedial measures might reduce the extent of adverse effects. They do so at a cost, however, and this cost is, in a way, wasted if it transpires that the hazard they guard against is harmless. It is of course true that this is so with every kind of insurance premium. The point is that, as long as events are uncertain, the cost of reducing probabilities and consequences about what might happen may be worth bearing.

Judgements as to whether preventive and remedial measures are worth the cost will turn on how serious the unwanted consequences are considered to be, how likely they are to occur, and the efficiency of the envisaged precautionary and remedial measures. Hence, we need to consider how to weigh a reduction of consequences with this or that likelihood against the costs of this reduction. This raises further ethical and political questions about what level of precaution the authorities should choose.

The EU generally adheres to the Precautionary Principle (CEC, 2000). The Precautionary Principle claims that, in cases where "there are reasonable grounds for concern that potential hazards may

affect the environment or human, animal or plant health” (p. 9), but where the insufficient or inconclusive nature of the scientific data precludes the risk from being “fully demonstrated or quantified or its effects determined” with certainty (p. 13), the authorities may be justified in acting (i.e. restricting the liberties of a person, company, or organization) to reduce the alleged risk.

Recommendations to improve transparency

A suggestion that might provide a helpful structure for the full explanation of a decision is presented below (OXERA, 2000):

- the decision was about X
- this is important because of Y
- the options were a, b, c ...
- advice was received from p, q, r; they were chosen because ...
- their advice was ..., and hence the consequences and risks of each option were ...
- in reaching the decision, account was taken of (e.g. international treaty obligations, long-term policies, implications for other areas of policy)
- the criteria adopted when considering the advice were ...
- where there was conflicting advice, p and q were accepted (and r rejected) because ...
- hence the decision is because ... (a summary of the earlier points, the values that were applied and the weight that was given to conflicting arguments).

Decision-making processes dealing with hazardous activities can be characterised as decision-making with multiple objectives and by preparation and evaluation of alternatives where objectives of different types and values are weighed. Some authors maintain that multi-criteria mapping provides a systematic and transparent tool for exploring assumptions in judgements about issues such as GM crops (ESRC, 1999) (Stirling & Mayer, 1999) (Keeney & Raiffa, 1993).

Risk reduction and management

Aim and characteristics

Risk management is a process of following up the decisions and actions in order to ascertain that risk containment or reduction with respect to a particular hazard is assured. It comprises analyses and choice of a particular course of preventive or remedial measures and actions from an array of possible control options, and accumulation of evi-

dence through monitoring and evaluation to support or give reasons for revision of assumptions and results of risk assessment plus follow-up on actions.

Problems and dilemmas

Risk management is a development and implementation of strategies which is by nature value driven. If precaution is intended to play a decisive role in the risk management phase, it must be included as a value already in the risk assessment phase.

Preventive and remedial measures can be rather expensive in terms of capital as well as time, and it is vital carefully to evaluate and balance the costs against obtainable benefits. Preventive measures are directed to the reduction of the probability/likelihood of adverse events, while remedial measures are directed to the reduction of the consequences/effects of adverse events. In cases in which the systems dynamics and scenario mechanism are correctly understood, the preventive and remedial measures will have the intended effect on probability/likelihood and consequences/effects. The scenario model can be used to pick out and present both where, in the course of the scenario, the measures are going to be implemented, and their expected function and impact.

Also, monitoring programmes can be expensive with long time horizons before evidence is gathered, and this can put pressure on the competent authorities with respect to not setting up approval conditions with significant monitoring requirements.

A question related to these conflicting issues is this: who is going to bear the costs, and who will get the benefits?

Recommendations and perspectives

Development of a risk management plan including (McColl et al., 2000):

- how and when the risk management strategy will be carried out
- the roles, responsibilities and accountabilities of individuals and organisations
- plans for information, communication and involvement of interested and affected parties
- criteria that will be used for monitoring and evaluation
- training requirements, staffing requirements and financing requirements
- periodically audit and review of control options and report any changes to the system.

It is recommended that intended benefits and expected costs of control options are thoroughly assessed and documented in order to make it clear to third parties how risk reduction and management are being carried out. The documentation of assessed preventive and remedial measures should contain argumentation for the selection as well as measures.

KNOWLEDGE AND COMMUNICATION IN ADVISORY PROCESSES

The scientific content of public policy decisions is growing rapidly. The relationship between science and government is an uneasy one, and a wide variety of advisory structures may be employed to support the policy-making process. Advisers operate at all levels of the political system, and the advisory process can be initiated in a number of ways, e.g. advice may be sought by the head of government, ministers or civil servants, or through legislation (Glynn et al., 2001).

The scientific advisory structure affects both knowledge generation and the selection of scientific input, and therefore the factual premises of a risk assessment. Transparency not only depends on the factual premises but also on how efficient knowledge is transferred, communicated and utilised within the scientific and policy communities. Efficient knowledge transfer is required if the actors are to achieve a common understanding of the factual premises of a risk assessment. Lack of common understanding between scientific advisers and policy-makers can lead to different understandings of the content and causal relations of the risk assessment, and this can lead to vague or unclear conclusions – and ultimately to lack of transparency. Therefore, it is important to address transparency issues that concern the process of generation, communication and transfer of knowledge and scientific results in appraisal procedures.

The communication and advisory process established around the preparation and application of a risk assessment differs from jurisdiction to jurisdiction. Despite these variations and differences, there are some key generic tasks and elements which are common for the majority of risk assessment procedures. These elements are discussed in the following section. They are viewed in the light of the issues discussed in the previous chapters of this report.

Knowledge

Knowledge transfer

Setting focus on transparency related to utilisation of scientific results in approval decisions, it is criti-

cal to be aware of the complexity of knowledge and knowledge transfer in relation to tasks and actors. When an individual performs, and communicates about, a task, the underlying knowledge types and their internal relations can be categorised in the way indicated in Figure 5 (Koskinen et al., 2003) (McBriar et al., 2003) (Choo, 1998) (Scharmer, 2001):

- *Tacit knowledge* that is not easily visible and expressible. Tacit knowledge is deeply rooted in an individual's experience; it consists of schemata, beliefs, and perceptions stored so deep in the worldview of an individual that we can take them for granted.
- *Explicit knowledge* that can be represented in words, drawings, plans, equations or numbers; this can easily be communicated between people.
- *Knowledge-not-yet-embodied* addresses phenomena like imagination and perceiving opportunities.
- *Cultural knowledge* consists of the shared beliefs, norms and values in which organisational members construct reality, recognise the relevance of new information and evaluate alternative interpretations and actions.
- *Personal characteristics*, such as stress toleration and competences, which either enhance or decrease an individual's ability to perform a task.

Knowledge that is more or less explicit can be represented in documents and databases and can be transferred with reasonable accuracy. Tacit knowledge transfer generally requires extensive personal contact. From a transparency point of view explicit knowledge can be made accessible and visible to third parties, whereas the underlying individual and institutional experiences, beliefs, perceptions and values rooted in tacit and cultural knowledge will generally be invisible to third parties. There are no easy ways to overcome these inhibitors of knowledge transfer. One way is to build relationships and trust through face-to-face meetings. Another way is to establish times and places

Figure 5. Knowledge tree - freely adapted from Koskinen et al (2003)

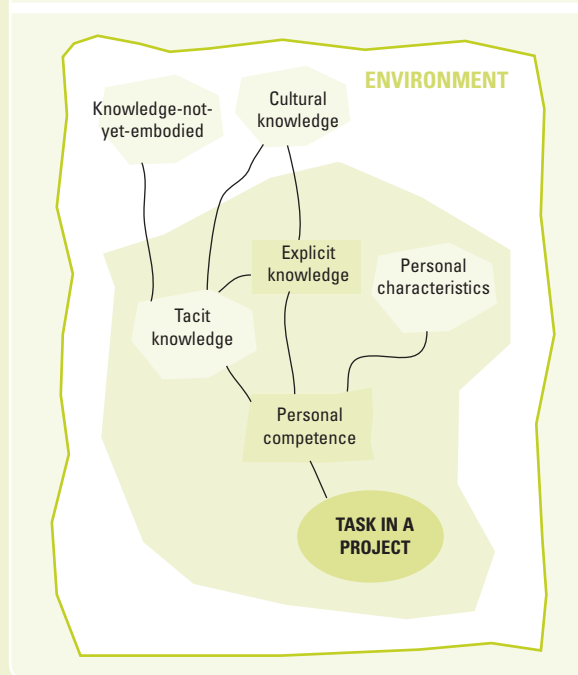
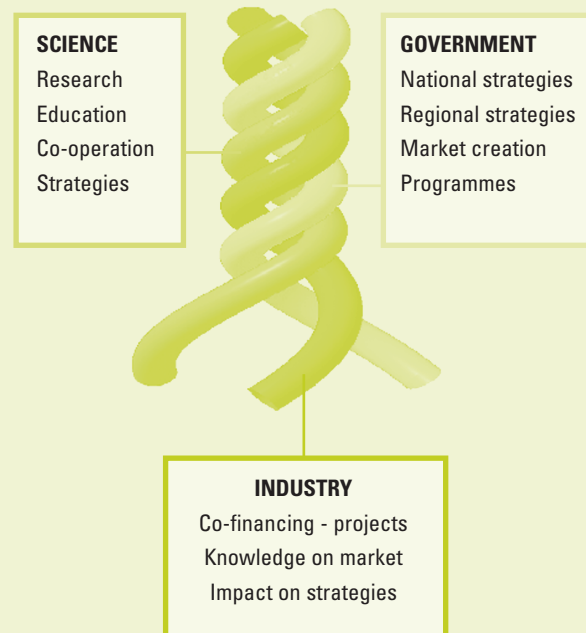


Figure 6. Triple helix model of innovation



for dialogue and participation, e.g. fairs, talk rooms, public meetings and conferences.

Knowledge production

The knowledge foundation utilised in an approval decision has to be regarded in a broad perspective covering the actor relations and the origin of the knowledge.

Triple helix model

One thesis is that the boundaries between public and private, science and technology, university and industry are in flux. University-industry-government relations can be viewed as a triple helix of evolving networks of communication and co-operation. Public and private organisations are assuming tasks that were formerly the province of the other sectors (Leydesdorff, 2000). The triple helix model argues that a knowledge infrastructure is generated in overlapping institutional spheres, with each taking the role of the other, and with hybrid organisations emerging at the interfaces (Etzkowitz & Leydesdorff, 2000).

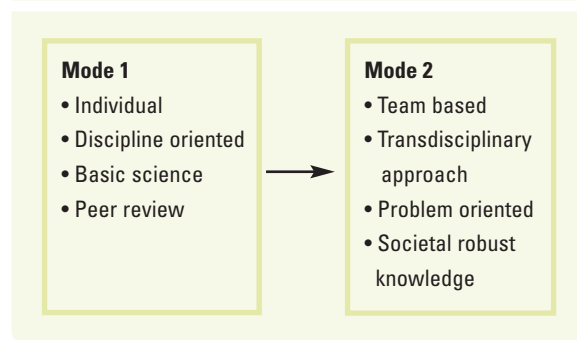
Putting transparency in the triple helix perspective, it can be asked how these new conditions for knowledge creation will influence transparency in appraisal procedures requiring scientific advice. In the public debate impartial and independent experts are frequently called upon, but from a triple helix perspective, arguing that a new knowledge creation infrastructure is under development, one consequence can be that the origin and providers of knowledge will be less obvious, and this will make it difficult to fulfil the requirement concerning utilisation of unbiased and balanced knowledge in government decision processes.

Mode-1 and Mode-2 knowledge

Another thesis has been formulated by Gibbons (1999). Gibbons says that a new social contract between science and society is under development. Under the prevailing contract, science has been expected to produce reliable knowledge, provided merely that it communicates its discoveries to society. Under the contract now in development, scientific knowledge must be socially robust, and its production must be seen by society to be both transparent and participative. This change in knowledge production is characterised by Gibbons et al. (1994) as a transition from Mode-1 knowledge production to Mode-2 knowledge

production. Mode-1 knowledge is generated within a disciplinary, primarily cognitive context. Mode-2 knowledge is created in broader, transdisciplinary, social and economic contexts. Mode-2 knowledge production has tended to erode the demarcation between traditional 'knowledge' institutions, such as universities and research institutes, and other kinds of organisation (Nowotny et al., 2001).

Figure 7. Transition from Mode-1 to Mode-2



The creation of knowledge in a transdisciplinary context involves different people with different perspectives and different ways of working. The research process will require tacit, explicit, and cultural knowledge from different disciplines and institutions. One of the challenges is to transfer knowledge between disciplines and institutions, and on that basis to create new knowledge. The resulting outcome can, on the one hand, be complex, which makes it less transparent. On the other hand, it can be reflexive and applicable, which makes it more socially robust. Due to the problem and application oriented approach, Mode-2 knowledge is context sensitive and highly specific. This raises the question to what degree Mode-2 knowledge will be transparent to people not familiar with the context. Finally, the significance of dialogue and open relationships in Mode-2 knowledge creation will open up the possibility of improved transparency.

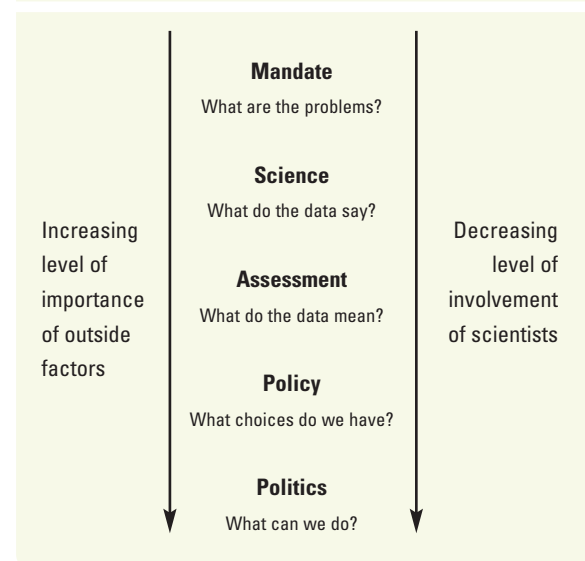
The science/policy decision-making process

As discussed in the previous chapter, a risk assessment cannot be characterised as pure science. It is

constrained by a range of limitations stemming from the mandate and decision context. In order to improve transparency, it is essential that the actors understand how their own and other actors' contributions are going to be used in the risk assessment, analysis and management process.

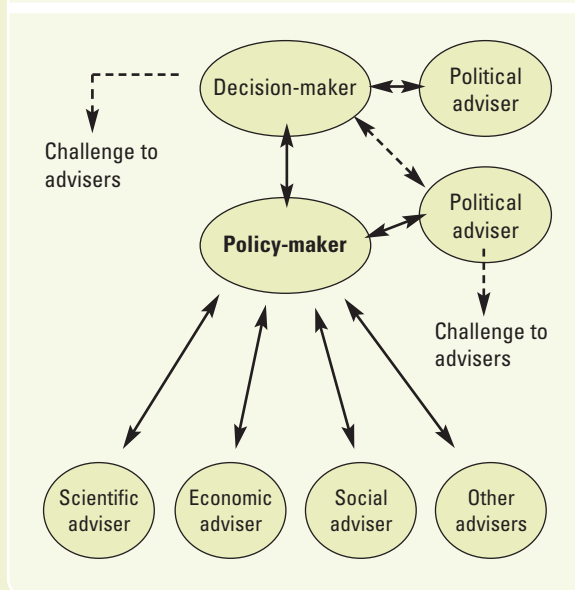
Traditionally, the science/policy decision-making process could be seen as a continuum, starting with definition of the mandate, followed by production of scientific information and knowledge, and an assessment process, leading to policy choices and, finally, political decisions. Along this continuum, there is a decreasing level of involvement on the part of individual scientists and their knowledge, and an increasing level of importance of non-scientific considerations, e.g. economic and social considerations, see Figure 8 (CCDM, 2002).

Figure 8. The science/policy decision-making process - freely adapted from CCDM (2002)



A set of generic functions and relationships in a policy decision can be listed (OXERA, 2000), see Figure 9.

Figure 9. Functions and relationships in a policy decision (OXERA, 2000)



These generic functions are used in our discussion of actors and their role in the science/policy decision-making process.

- *Decision-maker*: a person with the authority to make a policy decision.
- *Policy-maker*: a person or organisation charged with assisting a decision-maker in reaching a decision by providing policy analysis, generating policy options, or by conducting risk assessment.
- *Scientific adviser*: a person or organisation responsible for providing scientific input to policy-making or decision-making. This includes both scientists expert in narrow disciplines relevant to the problem in question, and more broadly-based scientists who are able to integrate several disciplines, and may involve those within and outside the civil service.
- *Stakeholder representatives*: a person or organisation representing the interests and opinions of a group with an interest in the outcome of a particular policy decision.

Scientific advisory structure

Dilemmas and concerns

Two contradictory concerns affect scientific advice: on the one hand, the need for advisers to be seen as independent is increasingly important (Glynn et al., 2001); on the other hand, the compe-

tent authority is expected to identify, comprehend and build their policy on robust and high quality knowledge in order to provide high-level expertise in advice to the government. Fulfilling the second concern can fundamentally change how scientists and policy-makers work with, and relate to, each other. The process of using science information to inform decision-making may become one where science/policy communication is regular and informative, teamwork and multidisciplinary initiatives are the norm, and science and policy staff work together in pursuit of shared objectives (CCDM, 2002). The two contradictory concerns one demanding independent advisory bodies, and the other asking for science and policy working close together to improve the scientific quality of the decision – can easily come into conflict, and this sets up a challenge for the competent authorities to build a robust, transparent and legitimate decision process.

Providing scientific advice for policy-making is a complex procedure involving and affecting a variety of actors with differences in perspective, competences and interests. For many scientists, the primary interest in these disputes is to draw the line between science and policy in ways that best preserve the authority and integrity of science, whereas other actors would draw this line in a way that maximises their control over social decisions. When focusing transparency in decision-making, it is crucial to reflect on the problematic nature of the provision of knowledge, on conflicting views on its application, and on its inseparability from context.

In principle, the competent authority can freely select scientific advisers. In real life there are at least two things to think about. It is an advantage to have close relationship between policy-makers and advisers, one based on dialogue and confidence. In smaller countries like Denmark resources are limited, and this means there are only a few competent scientific groups within a specific area. In practice, this limits the alternatives when scientific advisers are selected. Furthermore, the question of selection of scientific advisers is closely connected to the economic resources allocated for scientific advisory purposes (Kjær, 2004).

Risk assessment processes are often pressed, in terms of time and resources. Consequently, the risk assessors' work is pressured. Risk assessors are usually appointed by policy-makers to come up with a conclusion about the adverse effects of a substance and have a deadline by which this con-

clusion should be delivered. Time pressure can affect the resources allocated for a thorough review and the evaluation of available scientific literature. This in turn may mean that important conflicting scientific viewpoints are missed, resulting in less robust and clear argumentation and documentation.

The fact that research is privately funded also affects openness and transparency. Private companies currently conduct a significant portion of risk research, and private-sector research is likely to increase relative to publicly funded research. New technologies, e.g. gene technology, demand considerable specialised resources, making it nearly impossible for publicly funded research to achieve the same level of expertise. This means that regulation concerning risk and safety will largely rely on inputs from private research, and this will place public policy work in a demanding position with limited or no influence on knowledge creation, together with less access to high level expertise.

Finally, it is important to keep the appraisal procedure simple. The more complex the appraisal technique employed, the more vulnerable is the process to oversight, error or manipulation, with lack of transparency as a resulting effect.

Recommendations to improve transparency

The process by which scientific advice is generated should always be open to scrutiny. This helps to ensure freedom from bias and allows stakeholders to contribute to the advisory process. It is advisable to describe clearly the relations and correspondence between the applicant, the competent authority and the scientific advisers. An audit trail of the scientific advisory process could be made available to policy-makers, decision-makers and ultimately stakeholders. The audit trail might cover the generation of scientific questions; the scientific arguments, calculations and analyses; alternative scientific options and uncertainties; and the scientific appraisal of policy options (OXERA, 2000).

In a broader sense, training programmes for the policy community could provide information on the nature of the scientific process (CCDM, 2002). In this context, regular exchange of experiences between jurisdictions responsible for the regulation of hazardous activities can be constructive and help to show how to make the scientific advisory structure transparent.

Problem definition

Submission of application

The applicant prepares and submits a risk assessment to the competent authority containing the applicant's interpretation of the scope and content of the risk assessment.

In connection with an application for deliberate release a GMO for any purpose other than that of being placed on the market, the first contact between the applicant and the competent authority is established. Often the applicant is surprised by the legal requirements governing a risk assessment (Kjær, 2004). The applicant prepares the risk assessment, and where the extent of the legal requirements is not fully realised by him or her this can contribute to reduced transparency.

After receiving the application, the policy-makers have to decide on conditions, resources and a time schedule for the scientific advisory process, including identification and selection of scientific advisers and considerations concerning the involvement of stakeholders in the scientific advisory process.

Acceptable level of risk

Setting up criteria is one of the most difficult and controversial parts in risk decisions. The aim is to make the value premises clear for the subsequent risk assessment, reduction and management process.

The characterisation of unintended events and adverse effects is inseparably bound up with the objectives and the acceptance criteria. A precondition for setting up precise criteria for acceptable risk will be an identification of the different types of relevant adverse effect on human health and the environment. For each type of adverse effect it then has to be decided what total level of occurrence of this effect is acceptable. The distribution of the effect might also be normatively relevant: in some cases, it is reasonable to set a limit to the risk run by each individual.

Dilemmas and concerns

Risk acceptance criteria can be of qualitative or quantitative character. Risk acceptance criteria are normally to some extent stated in the legislation, but they can be of vague general character, leaving a large space for the applicant, the policy-maker as well as the scientific adviser to adapt or influence the acceptance criteria of a specific risk assessment process. The consequence can be an unclear

appraisal and approval process, where the origin or ownership of essential questions related to underlying value premises, trade-offs and risk levels are unclear or even lost.

In some cases (e.g. for GMOs) the legislation will list in detail which adverse effects should be considered, but not in all. Moreover, even a detailed list like this should not be read as exhaustive. Thus, in many cases, when approval for a new activity, process or product is applied for, the relevant types of adverse effect are not known in advance. And even to the extent they are, it seems unwise to decide on the level of acceptability before the exact level of occurrence is known. The decision problem is first fully described when the risk assessment is completed. It seems hazardous to decide on the normative criteria for approval without utilising the knowledge input provided by the risk assessment.

The problem is, however, that the risk assessment shall provide information on the relevant risks. It therefore has to take its departure from an understanding of which types of effect on human health or the environment it has to consider. Probably, a risk assessment will also benefit from an understanding of what the critical levels of occurrence are. If there was only one decision-maker who both decided on the normative criteria for acceptable risk and acquired the relevant factual knowledge by performing the risk assessment, this would not be a problem. In theory, at least, such a decision-maker would be able to jump from normative to factual premises, and the other way round, and make the necessary adjustments.

In practice, however, the decision on criteria of acceptable risk and the risk assessment are made by different persons who are even supposed to operate independently of each other. This makes it important that as many as possible of the authorities' normative considerations are communicated to the scientific experts before the risk assessment is undertaken.

In emerging technological domains (e.g. with GMOs) scientific considerations may help to identify criteria that were not apparent before. Therefore, here it shall be considered whether to keep the criteria and acceptability open until scientific advice has been taken.

The formulation of acceptance criteria can be confronted by unrealistic or idealistic standpoints. Often politicians and the public insist on having a "zero-level" risk society. In real life this is unattainable, leaving the policy-makers in situations with

no generally accepted decision option. Decisions have to be taken, and unrealistic or idealistic standpoints can lead to reluctance to participate in open discussions and make clear statements about acceptance criteria.

Recommendations to improve transparency

The multidimensional character of risk problems (see Figure 2) is important to bear in mind in defining the mandate. Transparency is improved if it is made clear how problems are sorted out, and if it is made clear which problems are included and which are left out of the appraisal procedure, and why.

Further, it would be an advantage if the affected temporal and geographical scales are identified at an early stage in order to consult key stakeholders being relevant for the specification of the mandate.

An important element is the specification of the task to the scientific advisers – e.g. in an audit trail. Within the EU it is common for specific terms of reference to be negotiated before a risk assessment is carried out. In our view, it would be natural if such written terms of reference describe the general worries that motivate the risk assessment and furthermore specify as far as possible the kind of knowledge considered relevant. The goal is to obtain a shared understanding of which hazards and which adverse effects should be considered.

The policy decision should not be delegated to scientific advisers by posing the questions in such a way that the scientific advice determines the policy option to be adopted. The policy-maker needs to anticipate, as early as possible, those issues for which science will be required, in order to facilitate timely and informed decision-making. That is, the policy-maker needs to be competent to specify scientific questions. The questions should be refined through dialogue between scientific advisers and policy-makers, and may be further refined through challenge by stakeholders (OXERA, 2000). Stronger involvement of stakeholders may make an important contribution to improvement of transparency at this stage by ensuring that the range of problems considered is appropriate.

Scientific advice to policy-makers

Concerns and points related to uncertainty

Because of the inherent uncertainties in risk assessment, values have more influence in risk assessment than in pure science. Lack of aware-

ness of value judgement in scientific communities, and maybe also the scientist's limited capability to explicate value judgements, will reduce the transparency of scientific advice as the underlying values will remain indistinct. Scientists are human, and so they carry their own inherent biases related to their professional training, past experiences and personal views. Often they are unaware of their personal biases and do not fully realise the extent to which prejudices can influence professional judgement.

Thus, the policy community must be aware of, and better informed about, the uncertainty of scientific knowledge. It is a challenge for science community to clearly express the meaning of the uncertainty to policy-makers. It is a challenge for the policy community to be able to understand and interpret the 'shades of grey' associated with uncertainty in scientific information together with the uncertainties related to the decision context, and translate that into 'black' or 'white' policy actions.

Coverage and completeness of risk assessment

Policy-makers need a description and evaluation of the coverage and applicability of the applied methodologies and data due to the scope and purpose of the risk assessment. This can include a systematic mapping of sensitivities reflecting context dependency, irreconcilable values, divergent option definitions, inconsistent framing assumptions, realistic assessments of the robustness of all conclusions, and description of new evidence which, if it were to emerge, would cause the adviser to change his or her advice (Stirling, 2001 & OXERA, 2000).

One of the gravest errors in any type of risk management process is the presentation of risk estimates which convey a false impression of accuracy and confidence. In no case should the existence of residual uncertainty be considered a reason for withholding results. Risk characterisation is the final vital stage in the risk assessment process. Perhaps surprisingly, the steps in the risk characterisation are by no means universally agreed. Judgement plays a key part, and it is necessary for this to be made transparent (European Commission, 2003) (McColl et al., 2000) (OXERA, 2000).

Recommendations to improve transparency

All participants in the advisory system should be trained in techniques for posing questions and operating the various advisory mechanisms. It is

especially important to focus on the transfer of tacit and cultural knowledge in order to explicate assumptions and values. E.g. the workshop held on 7 December 2004 with participation of scientific advisers and policy-makers indicated difficulties in communication and understanding between participants with differing education and contrasting roles in the appraisal process, and this lack of common understanding could be a source of reduced transparency.

It is recommended that there be face-to-face meetings between risk assessors and policy-makers in all steps of the appraisal process, with special emphasis on the distinction between analysing factual premises and assessing normative premises, and that the outcome of these meetings is documented in an audit trail.

At all times the scientific adviser should remain aware of the basis of the advice. Four such bases can be recognised, all of which are within the scope of scientific advice, but each of which merits a different level of certainty and involves different values (OXERA, 2000):

- Observation: empirical evidence that is unambiguous and uncontentious, although it may still be open to different interpretations.
- Formal analysis: which should lead to a consistent result, regardless of who conducts the formal analysis.
- Reasoned judgement: the outcome of a disciplined approach to a problem, whereby deductions are made by extrapolation or extension from the formal analysis.
- Opinion: simple assertion (i.e. a belief), the value of which depends entirely on the integrity, competence and credibility of the party expressing the opinion.

Data gaps, and the priority of requirements, should be clearly communicated to the policy-makers. Means need to be developed to show the provision and selection of key documentation and, where this is the case, the rejection of any substantive submissions. Central questions are (European Commission, 2003):

- the availability of suitable information on how the data was derived
- the quality of the experimental work
- the scientific standing in the field of the authors and their perceived independence
- whether the findings are consistent with the available literature in the field
- identification and recording all the sources of data that have been used

- reporting any important limitations of accessibility of potential significant data
- the weighting given to individual data sets and the rationale for this
- whether or not stakeholders have the opportunity to submit additional data
- the strategy for dealing with data gaps should be clarified during the risk evaluation step
- statement of what new evidence, if it were to emerge, would require the advice to be changed.

Hearings

Public

For the non-professional, the normative premises of the legislation can be very difficult to read owing, on the one hand, to the departmental language style, and, on the other hand, to difficulty finding a way through the regulatory framework jungle. Looking at the EU legislation on “Deliberate release into the environment of genetically modified organisms” as an example, the framework consists of a Directive supplemented by several Commission Regulations and Commission Decisions. Clarification of the normative premises of the legislation is important in order to explain to third parties the normative premises of the risk assessment.

The aim of public hearings is threefold: a) to give information to the public about new technologies, their consequences and the legislation setting the framework for the appraisal process, b) to collect comments, viewpoints and objections from stakeholders on the risk assessment, and c) to pass on viewpoints from public hearings to the parliament and the minister.

The hearing statements that come from professional organisations, such as NGOs, and ordinary citizens are often of very different character. Public hearings are one out of the few opportunities for the general public to express viewpoints within the policy system. Therefore, all sorts of comment and statement are expressed. The public hearings may be regarded as one of only a few battlefields for debate on future application of new technology, and consequently as a forum in which a multitude of actors vie to further their interests. Some hearing statements are purely scientific. Others are more moral or political. Due to this variety, it can be difficult to give consistent and transparent treatment of the hearing statements.

Recommendations to improve transparency

When risk assessments are submitted to hearing

partners it should be made clear how the hearing statements will be used in the appraisal procedure and which topics will require comment, i.e. topics contained within the legislative frame. Afterwards, feedback should be returned to hearing partners indicating the impact of the hearing statements in the approval process.

EU

Decisions about risks are to a large extent taken in the EU. Mutual information is exchanged between EU member states about new technologies and their areas of application. This includes the collection of comments, viewpoints and objections from EU member states and EU committees on hazardous activities.

This prevalence of supranational procedures for risk assessment can influence the transparency in two ways. The documents and discussions are carried out in English, and this probably leads to lack of transparency for the public in general. For the professional actor, common EU rules can lead to improved transparency (Kjær, 2004). It is recommended, that all documents are available in national languages.

The reviews from member states can contain both strictly scientific arguments and expressions of national preference. There might be disagreements between the countries, and there might be national preferences which not are scientifically motivated. It may be inadvisable to state national preferences clearly, as this can be regarded as setting up a technical trade barrier. National preferences might be wrapped up and blurred within a scientific set of arguments, and the resulting mixture of risk, science, local and national interests can be very hard to see through.

Stakeholders

Stakeholders have an important part to play in ensuring that the scientific questions being asked are pertinent to the policy issues that are of concern to them. However, active and direct participation by stakeholders in the generation of scientific advice itself could lead to the generation of scientific advice that is based on value judgement and stakeholder views rather than expert analysis of scientific evidence (OXERA, 2000). Another controversial element is the identification and selection of stakeholders who are given (or not given) the opportunity to submit input to the risk assessment.

Recommendations to improve transparency

It is recommended that there be a transparent procedure and a well-documented process for the identification and selection of stakeholders.

Expert committees

Expert committees are expected to provide objective, unbiased input to the approval process, e.g. ensuring that all relevant aspects and information from an expert point of view are identified and considered during the appraisal process. In principle, their role is similar to that of the scientific advisers, and consequently they are vulnerable to the same problems and dilemmas related to transparency.

Recommendations to improve transparency

It is recommended that there be a transparent procedure and well-documented process for the identification and selection of expert committees. The role of the expert committees should be clearly specified, and it should be clearly explained what types of expert committee are to be consulted and why.

Draft positions to decision-makers

Evaluation of scientific advice

The policy-makers have to evaluate the scientific advice and other types of input, such as hearings, to ensure that the documents cover the questions addressed in the legislation and provide a sufficient basis for draft positions on policy actions.

Preparation of scientific advice to decision-maker

The policy advice shall be strictly within the legislative requirements, and in cases where there is compliance with the technical requirements in the legislation, the applicant can anticipate receipt of an authorisation. Often other viewpoints will have been accentuated in hearing answers (e.g. arguments for or against the possibility of the formation of a monopoly following the approval of a GMO), and in order to improve transparency it is essential to make clear to third parties which issues that are contained in the legal framework and which are not.

While scientific information is intended to be a neutral description, or statement of facts, that details and distinguishes what is known from what is not, policy advice recommends a course of action. The decision-making process can be

encumbered with uncertainties (e.g. concerning agenda-setting or alternative solutions), and policy-makers have to reflect the values, and differences in the values, of the society and/or the groups they represent not only in the problems and concerns they choose to address, but also in the solutions they consider and the trade-offs they are willing to make.

Recommendations to improve transparency

When presenting the policy options to the decision-maker, the policy-maker should make clear the implications and robustness of the scientific analysis. This might be achieved by characterising the policy options according to (OXERA, 2000):

- expected and possible worst-case outcome
- the degree of reversibility of the option
- sustainability – whether the option can be sustained in the long term
- any precautionary arguments that may be relevant
- the reliability of the key assumptions and evidence
- the source of the advice, and the weight that should be attributed to that source.

Presentation and communication

Care should be taken to avoid a form of ‘openness’ that actually obscures key messages through obscure terminology or dilution of detail in large volume. Detail should be available to the expert reviewer, but the aim of this principle is effective communication with the public. This requires transparent communication of the key findings, including uncertainty (OXERA, 2000).

Decision-makers may find that it is useful to explain how scientific advice and other kind of input was taken into account in a policy decision. This would confirm that the scientific advice has been correctly understood, and that it provides assurance to the stakeholders that the issues of concern to them have been addressed. It would provide valuable feedback to the scientific advisers and hence contribute to the continual improvement of the scientific advisory system (OXERA, 2000).

CLOSING REMARKS

The report contains our reflections and considerations concerning transparency in decision-making processes dealing with hazardous activities. Our intention has been to explain, discuss and recommend issues related to content as well as the advisory process and the interaction between content and process. Our experience is that improving transparency in risk decisions is a difficult task as it involves a huge variety and complexity of premises combined with an advisory process involving actors with different functions and educational backgrounds.

These difficulties were clearly demonstrated in the workshop held as part of the project (see Appendix 1). The lessons learned there were that uncovering the values in risk assessment is tricky and something to which many are unaccustomed. It might be necessary to build up new competences in both the scientific and policy communities if argumentation and presentation of the normative and factual premises is going to be an element in future risk assessment and management. Further, it was learned that sessions across jurisdictions responsible for risk assessment and risk management can be valuable in allowing an exchange of experiences.

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APPENDIX 1:

WORKSHOP AND CASES

Workshop: 7 December 2004

A cross-institutional workshop was held on 7 December 2004 as part of the project. The participants were invited from the policy community as well as the scientific community. Together the participants represented a huge variety of disciplines, job functions and jurisdictions. The idea was to identify, reflect on, and reach a common understanding of, the values in three specific risk assessments:

- a glyphosate resistant fodder beet
- penta-bromo diphenyl ether
- vanadium

The workshop was a mixture of presentations and group sessions. The main tasks in the group sessions were to concentrate on identified hazards, adverse effects, uncertainties, risk characterisation and criteria for risk acceptance. The main outcome from the group sessions is summarised below.

Risk assessment of glyphosate resistant fodder beet

The risk assessment was done in connection with an application concerning the placing on the of a fodder beet tolerant to the herbicide glyphosate (notification C/DK/97/01). An evaluation was carried out by the competent Danish authority. Also, the Scientific Committee on Plants in the EU was asked its opinion on whether the genetically modified fodder beet is likely to have adverse effects on human health and the environment.

The risk assessment was carried out according to Directive 90/220/EEC. The directive states that the risk assessment should consider whether the use of the genetically modified fodder beet gives rise to adverse effects on human health and the environment. The use of the herbicide glyphosate as such is not covered by the risk assessment (but has to be evaluated on its own, according to Directive 91/414/EEC).

The risk assessment does not explicitly set out the criteria considered relevant. However, in con-

nection with adverse effects on human health, the following adverse effects are considered: *toxic effects of the produced enzyme*, *allergenic effects* due to the genetic modification and *health risks from using the beet to food production* due to the genetic modification. On the basis of experiments on a soy bean modified with the same gene, and on the absence of any reason to believe conditions to be different for the fodder beet, it is concluded that the fodder beet does not give rise to health problems.

Concerning adverse effects on the environment, the following can be noted: *establishment and subsequent invasion of the modified fodder beet outside cultivated areas* and *ecological consequences of hybridisation with the wild relative Beta maritima*. In a number of experiments, no significant difference to the unmodified fodder beet in terms of competitiveness has been observed, so it is concluded that no ecological effects are to be expected from establishment outside cultivated areas. Furthermore, since glyphosate is not used on or near seashores, there are no ecological consequences to be expected from spread of the gene to *Beta maritima*.

Finally, the adverse effect of *spread of the resistance gene to weed beet* is evaluated. One possible adverse effect was mentioned during the exercise by the experts as not examined: adverse effects on biogeochemical cycles.

When it comes to uncertainty, it is clear that the experimental evidence is somewhat limited in time horizon: there is no experience of the long term effects of growth or foddering. It is possible to set up alternative scenarios concerning, e.g., invasion of the fodder beet outside cultivated areas. The risk assessment is concerned with the necessary conditions for this scenario to occur. The improbability of the scenario is based on the absence of evidence of any competitive advantage. Similarly, exclusion of scenarios with ecological consequences of gene-spread to *Beta maritima* is based on the improbability that glyphosate would be used on or near seashore areas.

Thus, even though the experimental evidence

is somewhat limited and alternative scenarios can be envisaged, the fodder beet is able to remind us that uncertainties should not be overstated.

Risk assessment of penta-bromo diphenyl ether

This risk assessment was carried out in accordance with Council Regulation (EEC) 793/93 on the evaluation and control of “existing” substances. “Existing” substances are chemical substances in the use within the European Community before September 1981 and listed in the European Inventory of Existing Commercial Chemical Substances. Regulation 793/93 provides a systematic framework for the evaluation of risks to human health and the environment presented by these substances if they are produced or imported into the Community in volumes above 10 tonnes per year.

The methods for carrying out an in-depth risk assessment at Community level are laid down in Commission Regulation (EC) 1488/94, which is supported by a technical guidance document.

All identified risks are associated with the manufacture and use of penta-BDPE in polyurethane products. However, it cannot be excluded that there may be uses of the substance not covered by the risk assessment.

Roughly, the risk assessment should, within each area considered, conclude in one out of these three ways: (i) There is a need for further information and/or testing; (ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already; or (iii) There is a need to limit the risks.

Concerning the environment, the risk assessment estimates ‘predicted no effect concentrations’ (PNECs) for aquatic and terrestrial compartments. These are then compared with ‘predicted environmental concentrations’ (PECs). Also, secondary poisoning in the food chain is considered. A PEC/PNEC ratio greater than one gives reason for concern. Finally, abiotic effects in the atmosphere are considered.

Risks to the atmosphere and those arising from regional emissions to the aquatic environment (in both surface waters and sediments) have been found to be acceptable. As for secondary poisoning, a need for risk reduction measures has been identified: PEC/PNEC for the fish-based food chain is estimated at 2.2; and PEC/PNEC for the earthworm, based on the food chain, is estimated at 1.7.

Concerning human health, a number of adverse effects are considered: acute toxicity, irritation of the skin, eyes and respiratory tract, corrosivity, sensitisation of eyes and respiratory tract, mutagenicity, carcinogenicity and toxicity vis-à-vis reproduction. Exposure is assessed for workers and consumers; indirect exposure via the environment is also assessed, as is combined exposure and exposure to infants via milk.

There are no data on the toxicological effects of penta-BDPE in humans. Also, exposure assessments are rather uncertain. The risk assessment concludes that consumer exposure is negligible, whereas there is a need for further information and/or testing concerning the other forms of exposure.

In this case, there are uncertainties at many levels. Particularly concerning human health, there is no certain hazard identification and considerable limitations in the possibilities of obtaining results from humans. Also, exposure assessments are difficult to make. For a substance like this, the proposal for a new decision procedure, based on the Precautionary Principle, concerning substances which are persistent, bio accumulating and toxic, might involve clearer criteria for decision makers.

Risk assessment of vanadium

In 2002, the European Parliament and the Council adopted Directive 2002/46/EC on food supplements containing vitamins and minerals. In addition, the Scientific Committee on Food (SCF) issued, from October 2000 to April 2003, a series of opinions on tolerable upper intake levels of individual vitamins and minerals and safety factors in relation to their use in fortified foods and food supplements. The SCF opinions covered 22 out of the 29 nutrients which were considered to be within their mandate for this task. Therefore, the European Food Safety Authority was asked to provide similar scientific opinions on the remaining 7 vitamins and minerals, plus an additional 5 (including vanadium).

The hazard identification is limited to oral toxicity data (except for carcinogenicity). Hazards from inhalation and the medical occupation have been reviewed in other contexts. The following adverse effects are considered: acute toxicity, sub-acute/subchronic toxicity, carcinogenicity, genotoxicity, reproductive and developmental toxicity.

In humans, gastrointestinal difficulties caused by doses as low as 0.2 mg/kg body weight/day have

been reported. In rats, vanadium compounds affect kidneys and other organs at relatively low doses, and at higher doses they have adverse effects reproduction and the development of the offspring of rats and mice. These effects have not been demonstrated in humans, but there is no evidence that they cannot occur.

The mean dietary intake of vanadium is estimated to be about 0.2-0.3 µg/kg bodyweight which is at least three orders of magnitude below the lowest dose reported to have adverse effects in rats (800 µg/kg body weight) and in humans (200 µg/kg body weight).

A 'no observed adverse effect level' (NOAEL) cannot be derived from the available subacute and subchronic studies on rats, nor can it be derived from developmental toxicity studies on rats. Hence, the available data are insufficient to show the highest level of oral intake that can be regarded as tolerable. There is uncertainty about the critical levels as well as about exposure.

There is concern about athletes and body builders who use vanadium in supplements, although the effects of this have not been documented in humans. For these groups, the daily intake may be similar to the doses reported to cause gastrointestinal effects in humans and kidney lesions in rats.

The fact that there is no documented positive effect of vanadium might be relevant in risk management decisions. The absence of benefits might justify a stricter regulation than would be suitable in cases where, because of the expected benefits, it is considered acceptable to run some risk.

APPENDIX 2:

METHODOLOGICAL BASIS AND BIOGRAPHICAL NOTES

The project was carried out within the framework of the Danish Centre for Bioethics and Risk Assessment, a cooperation platform of four universities and research institutions in Denmark. Methodologically, the project presents reflections on how to increase transparency of decision-making. The basis of these reflections is studies of relevant literature and interviews with key persons within the area. The reflections draw on concepts and theories from many disciplines, e.g. risk assessment, systems thinking, decision theory, science sociology, engineering and philosophy. They of course also draw on our professional experience, see below.

Biographical notes

Birgitte Rasmussen

MSc (Chem. Eng.), PhD (risk assessment). BR is senior scientist in the Technology Scenarios Research Programme at the Systems Analysis Department at Risø National Laboratory. Her main areas of work are technological risk assessment, technology foresight, dialogue processes, knowledge dynamics & practices and the interaction of science and industry. BR has 15-20 years experience in R&D joint projects with researchers, industries and authorities within the fields of industrial safety, food safety, biotechnology, nanotechnology, and sensor technology. In her research, she is engaged in the development of theory and methodology for technology mapping and systems thinking and the influence of such mapping and thinking on the outcome of technology studies.

Karsten Klint Jensen

MA, PhD (Philosophy). KKJ is senior researcher at the Royal Veterinary and Agricultural University. During the last 10-15 years, he has participated in several major interdisciplinary research projects in fields such as bioethics, ethical accounting for animal husbandry, landscape management, genetic modification of crops, risk perception of zoonoses, participatory procedures and democratic legitimacy, the interplay between risk management,

uncertain knowledge and risk communication and transparency in decision-making processes dealing with risky activities. His research lies primarily within ethical theory and applied ethics. A dominant theme has been the interface between ethics and other disciplines, e.g. economics, decision theory, animal welfare studies, environmental science, risk assessment and risk perception studies.

The **Danish Centre for Bioethics and Risk Assessment (CeBRA)** performs interdisciplinary research on ethics, risk issues and other societal aspects regarding the performance and results of biological sciences. Researchers with their background in social sciences and the humanities as well as in natural and applied sciences are involved in CeBRA's projects. CeBRA is jointly owned by the Danish Institute of Agricultural Sciences, Risoe National Laboratory, the Royal Veterinary and Agricultural University and the University of Copenhagen. Its project grants come mostly from Danish and European public funds and some also from industry.

In 2001 the Danish Parliament launched the **BioTIK project**. It was a four-year project focusing on both the possibilities that gene technology offers, and the ethical principles that are to be considered in order to make the right decisions. BioTIK is a Danish abbreviation of biotechnology and ethics. Hence nine Danish ministries joined a Task Force with the purpose to incorporate ethical principles in regulation of biotechnology, in decision making processes and as a basis for public debate and information.

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